

REMARKS

Applicant's attorney wishes to thank the Examiner for the careful consideration given this case. Claims 1-3, 5 and 7-16 are pending in this application. Claims 1, 13 and 16 have been amended. Support for all amendments can be found in the specification as originally filed. For example, support for amendments to claims 1 and 16 can be found in paragraphs [0034], [0036] and [0040] and Fig. 5, and support for amendments to claim 13 can be found in paragraphs [0030] and [0036] and Figures 4-6. Accordingly, no new matter has been added.

Rejection under 35 U.S.C. § 112

Claim 13 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim what the Applicant regards as the invention. The Examiner alleges that the described position of the tapered mount is inconsistent with the specification as described in the drawings. Applicant respectfully disagrees and submits that each of Figs. 1-7 show the tapered mount positioned *upon* the distal end of the connecting rod. However, in the interest of expediency, Applicant has amended claim 13 to read that the tapered mount is positioned "at" the distal end of the connecting rod. Applicant submits that amended claim 13 complies with 35 U.S.C. § 112, second paragraph. Accordingly, reconsideration and withdrawal of the Examiner's rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-3, 5, 7-9 and 14-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,586,986 to Hinchliffe.

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First and foremost, Hinchliffe fails to disclose a device having a needle trap mechanism that is operative to draw said angled needles proximally into the lumen of said cannula as recited in amended independent claims 1 and 16. In contrast, the needles of Hinchliffe become latched in a latch member (col. 5, lns. 41-45), retained in suture carrying heads or compliant material (col. 6, lns. 8-28), mechanically retained in a skin guard (col. 8, lns. 26-27) or frictionally retained in retaining pockets (col. 9, lns. 6-9). In each embodiment described after emerging from the incision, the needles become attached to a substrate by the force produced to drive the needles through the tissue and are retained outside of the cannula. No other force is applied to the needles and, therefore, the needles are never provided with the force necessary to *draw* them into the cannula. Hinchliffe fails to disclose or even contemplate this step nor does Hinchliffe provide a means for drawing the needles into the lumen of the cannula.

Furthermore, Hinchliffe fails to disclose a device having angled needles. In fact, the needles of Hinchliffe (12 and 14) are illustrated and described as being “curved” (see, for example, col. 4, lines 39-41) and not angled. Applicants have amended independent claims 1 and 16 to clarify that the angled needles of the current claimed invention “are capable of traversing at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula”. Applicants submit that the curved needles which are described in the art necessarily traverse tissue in an arc and are incapable of traversing a tissue layer in a generally perpendicular orientation that is generally parallel to the cannula, as claimed. Additionally, Applicants submit that the claimed path provides significant advantages over curved needles because traversing at least one tissue layer in a perpendicular orientation that is

parallel to the cannula allows more tissue to be gathered and effects a more secure closure (see [0036] of specification as filed).

At least for the reasons described above, Hinchcliffe fails to disclose each and every element of the amended claims and, therefore, fails to anticipate amended independent claims 1 and 16. Accordingly reconsideration and withdrawal of the Examiner's rejection is respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 10-12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hinchliffe in view of U.S. Patent No. 5,860,991 to Klein et al. (hereinafter "Klein").

As described hereinabove, Hinchliffe fails to teach or suggest a needle trap mechanism that is operable to draw the needles into the lumen of the cannula or a device having angled needles that are capable of traversing "at least one tissue layer in an orientation that is generally perpendicular to the tissue layer and generally parallel to the cannula" as recited in amended independent Claim 1. Klein fails to cure these deficiencies.

Specifically, Klein fails to describe a device or mechanism whereby needles alone are drawn into a cannula. Instead, Klein teaches a mechanism wherein needles are captured by a stop member, a handle is released allowing the shaft to disengage from the needles and the entire device is drawn through the sheath (col. 8, lns. 14 – 26, Figs. 8-11). Additionally, Klein fails to describe a device having angled needles. Rather, the needles of Klein are consistently illustrated as being curved, and because the Klein fails to provide a mechanical mechanism for drawing the needles inward to ward the needle trap mechanism after entering the tissue layers, the device of Klein would be inoperative if angled needles were used in place of the curved needles illustrated.

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Therefore, Klein could not have contemplated the use of angled needles in the device described in the cited reference.


For at least these reasons, the combination of Hinchliffe and Klein fails to describe all of the limitations of amended independent claim 1 and this combination of references fails to obviate the current claimed invention. Claims 10-12 depend from and add further limitations to amended independent claim 1 and are allowable for at least the same reasons as amended independent claim 1. Accordingly, reconsideration and withdrawal of the Examiners rejection is respectfully requested.

CONCLUSION

In view of the amendments and remarks presented hereinabove, Applicant submits that the pending claims are in condition for allowance and respectfully request that they be passed to issue. Should the Examiner have any questions or comments, or need any additional information from Applicant's attorney, she is invited to contact the undersigned at her convenience.

In the event that any additional fees are required with this submission, the Commissioner is hereby authorized to charge or credit such fees to Deposit Account No. 50-0436.

Respectfully Submitted,

By: 
Raymond A. Miller
Reg. No. 42,891

Pepper Hamilton LLP
One Mellon Center, 50th Floor
500 Grant Street
Pittsburgh, PA 15219
(412) 454-5000
(412) 281-0717 - FACSIMILE
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